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IN THE

Supreme Court of the United States

OCTOBER TERM, 1965

No. [redacted] 187

STEVAN DUROVIC,

Petitioner,

vs.

ROBERT N. PALMER, R. D. SHERMAN, R. W. CASE, HON. ANTHONY J. CELEBREZZE, BOISFUILLIET JONES, AND JOHN H. QUILL, JR.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT.

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THE GUNTHORP-WARREN PRINTING COMPANY, CHICAGO

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Petitioner prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Seventh Circuit entered on March 5, 1965, in cause 14651.

OPINIONS BELOW.

The court below affirmed, with one dissent, the District Court decision granting respondent's motion to dismiss and motion for summary judgment of dismissal.

The decision of the District Court is appended hereto as Appendix A. The judgment order is appended hereto as Appendix B. The decision of the Court of Appeals affirming the decision of the District Court is appended hereto as Appendix C.

JURISDICTION.

The judgment of the Court of Appeals for the Seventh Circuit was entered on March 5, 1965. The jurisdiction of this Court is invoked under 28 U. S. C. 1254(1) (1958).

QUESTIONS PRESENTED.

1. Whether an action by an individual to enforce the Constitutional guarantee against unreasonable searches is an unconsented suit against the United States.

2. Whether the respondents violated the Fourth Amendment to the United States Constitution and The Federal Food, Drug, and Cosmetic Act by subjecting the petitioner to unreasonable searches and seizures.

3. Whether the District Court was in error in granting respondent's motion to dismiss and motion for dismissal on summary judgment without taking evidence on disputed questions of fact.

STATUTE AND CONSTITUTIONAL PROVISIONS INVOLVED.

The statute involved in this case is Section 374 of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 374 (1962), which in pertinent part provides that:

"(a) For the purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter at reasonable times, any factory, warehouse, or establishment in which *** drugs *** are manufactured, processed, packed, or held ***; and (2) to inspect, at reasonable times, and within reasonable limits and in a reasonable manner, such factory ***." "*** Each

such inspection shall be commenced and completed with reasonable promptness ***."

The constitutional provision involved is Article IV of the Amendments to the United States Constitution, which provides in part as follows:

"The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated ***."

STATEMENT.

This action was commenced in the United States District Court for the Northern District of Illinois. The District Court held that no claim had been stated in the complaint upon which relief could be granted.

1. This action arose under the Fourth and Fifth Amendments to the Constitution of the United States, as herein more fully appears. The matter in controversy exceeds, exclusive of interests and costs, the sum of Ten Thousand ($10,000.00) Dollars. Petitioner does not have a plain, speedy and efficient remedy at law.

2. It appears to the petitioner that the defendants are engaged and are about to engage in acts and practices which constitute and will constitute violations of the petitioner's right to be free from deprivation of his liberty without due process of law, and which subject to his premises to search and his possessions to seizure, in violation of his Constitutional right to be free from unreasonable searches and seizures.

3. The respondents Robert N. Palmer, R. D. Sherman, and R. W. Case are agents and inspectors of the Food and Drug Administration, which is a division of the United States Department of Health, Education and Welfare; the Honorable Anthony J. Celebrezze, a respondent, is secre-

tary of the said Department of Health, Education and Welfare, and by virtue of his office is responsible for and nominally in charge of the activities of all the members of that Department, including the other respondents herein; the respondent Boisfeuilliet Jones is Special Assistant to the said Anthony J. Celebrezze, in matters of Health and Medical Affairs; and the Respondent John H. Guill, Jr., is District Director of the said Food and Drug Administration, with his office in Chicago, Illinois.

4. The petitioner Stevan Durovic is a medical doctor, and a citizen and resident of the State of Illinois. In 1947 he discovered an anti-cancer drug known as Krebiozen, and is the owner of a concern known as Promak Laboratories, 1020 South Wabash Avenue, Chicago, Illinois, which currently is the producer of the said Krebiozen.

5. On or about June 8, 1963, a Saturday, the said respondents Robert N. Palmer, R. D. Sherman and R. W. Case, and each of the other respondents, unlawfully conspired with each other to act beyond their authority as said Food and Drug Administration agents and inspectors, and agreed that they would and in fact they did abridge the Constitutional rights of the petitioner as guaranteed by the said Fourth and Fifth Amendments thereto, and the petitioner sustained damages by reason of the said deprivation of his Constitutional rights, as will hereinafter appear more fully.

6. On the said June 8, 1963, the petitioner Stevan Durovic returned about noon to his laboratory at the said Promak Laboratories from Washington, D. C., where the day previously he, accompanied by one Dr. Andrew C. Ivy, a noted physiologist and researcher in the drug, had filed a plan of research and a notice of claimed investigational use for the said drug Krebiozen with the Food and Drug Administration, pursuant to the provisions of Section 505(n)

of the amended Food and Drug Act and regulations then going into effect. The said filing followed a conference held June 5, 1963 in the office of the respondent Boisfeuilliet Jones, during which the said petitioner and Dr. Ivy were given to understand by the said respondent that if they complied in good faith with the new filing requirements for continued experimental work with Krebiozen, the distribution of the drug could be continued to patients, including those now under treatment and ostensibly dependent upon its continued use for their lives and health, and that the said Department of Health, Education and Welfare would proceed in equally good faith as soon as possible to give attention to the application now pending for an unbiased clinical test of the said drug.

7. At the said time and place the said respondents Robert N. Palmer, R. D. Sherman, and R. W. Case, who had been lurking surreptitiously in the shadows of the hallway, followed the petitioner Stevan Durovic into his laboratory notwithstanding they knew that the said Promak Laboratories' business hours are exclusively from Monday through Friday, each week, from 9:00 A. M. to 5:00 P. M., and never on Saturdays, by virtue of the respondents Robert N. Palmer and R. D. Sherman, in association with another inspector, one Scheno, having from February 18, 1963 until they completed their inspections on or about May 28, 1963, been on the said premises on at least eight occasions between the said hours, while photostatting more than five hundred medical case files and receiving other data and various materials, including many finished samples of the said drug Krebiozen.

8. The respondent Robert N. Palmer stated to the petitioner Stevan Durovic that the Report he had submitted to Washington at the conclusion of his inspections in May, 1963, had been called "unsatisfactory" by his superiors;

that he had been ordered to prepare a new one, and that the respondent R. W. Case was replacing Inspector Scheno.

9. The said three defendants then demanded that the petitioner Stevan Durovic demonstrate to them the process used in filling ampules of Krebiozen, notwithstanding his objection that the technician who performs the operation was not at work, and that the said operation itself had been fully explained and demonstrated to the inspectors during the prior regular inspection.

10. Upon the further insistence of the said respondents, the said petitioner undertook to give a demonstration, and in so doing he took a container of Krebiozen from its storage place and poured some into a bottle which originally had contained pure distilled water. After the petitioner had attached tubes to the bottle and was explaining the process to the respondent Robert N. Palmer, the respondent R. W. Case stepped quickly forward, seized the bottle and turned it around approximately 180 degrees, whereupon the respondent R. D. Sherman suddenly produced a camera and snapped a picture featuring a label thereon saying, "Neptune, Hinckley & Schmitt, pure distilled water * * *", which connoted its contents and had not been removed.

11. The said photograph is calculated to create the erroneous, false, and fraudulent impression that the petitioner was pouring only distilled water into ampules, and the petitioner demanded that his secretary, one Helen B. Clark be permitted to take a dictated statement from him as to the true circumstances of Krebiozen having been placed in said bottle. Said statement was prepared and although the said three respondents agreed that it was correct in every detail, and were prepared to sign the same, they subsequently all refused to sign it after the respondent Robert N. Palmer made a long distance telephone call to Wash-

ington, D. C., and purportedly talked with his superiors there.

12. The building in which said laboratories were located was to be closed at 5:00 P. M., the respondents detained the petitioner against his wishes for more than two hours thereafter, during which time the said petitioner summoned one of his attorneys, James L. Griffin, Esq.; one Michael A. Batina, a laboratory aide and a regular part-time employee; and one Dr. Reginald Rabadan, a doctor of divinity, who also is a sometime assistant in the laboratory. When the building custodian threatened to summon Chicago City Police to clear the building according to his instructions from the building management, the respondent Robert N. Palmer paid the said custodian a sum of money purporting to be "overtime compensation" to permit them to continue to detain the plaintiff on the premises against his will.

13. For fourteen (14) years the petitioner Stevan Durovic has earnestly sought a clinical test for Krebiozen by the duly constituted authorities of diverse medical professional institutions and organizations as well as by the National Cancer Research Institute, the National Institute of Health, and the U. S. Public Health Service, and the Food and Drug Administration, and at all times he and his associates in the discovery, development and testing of the said drug have met all legal requirements and they have made a complete disclosure of all data and information in their possession concerning the said drug.

14. Among spurious accusations of the petitioner Stevan Durovic by diverse persons seeking to frustrate his scientific research and his incessant efforts to obtain a fair and unprejudiced clinical test of the said drug Krebiozen and its properties as an agent in the treatment of cancer, have been false and fraudulent innuendoes, and the said photograph, taken falsely and fraudulently by the said respondents R. D. Sherman and R. W. Case, is calculated to and if

circulated will cause the petitioner great and irreparable harm because of the wholly false and unwarranted impression that it will create.

REASONS FOR GRANTING THE WRIT.

1. The Fourth Amendment to the Constitution of the United States prohibits unreasonable searches and seizures, and its provisions must be rigidly enforced, *Hall* v. *U. S.*, 279 F. 2d 389 (1960); *Baysden* v. *U. S.*, 271 F. 2d 325 (1959). The framers of the Constitution did not intend the Fourth Amendment to permit an occasional unreasonable search nor did they intend that those responsible for its enforcement permit agents of the executive department—under the guise of public protection—to harass and encroach upon the constitutional rights of the individuals inspected. The Fourth Amendment should "* * * receive liberal construction so as to prevent stealthy encroachment upon or a gradual depreciation of rights secured * * * by imperceptible practice of courts or by well-intentioned, but mistakenly over zealous, executive officers," *U. S.* v. *Castle*, 138 F. Supp. 436, 439 (1956); *Gouled* v. *U. S.*, 225 U. S. 298, 303-304, 41 S. Ct. 261, 263, 65 L. ed. 647 (1920).

As applied to the petitioner, the foregoing standard has not been maintained. The respondents did not confine their inspections to the regular business days of the petitioner, nor did they confine their investigations to the regular business hours. On one instance the respondents detained the petitioner against his will for approximately two hours beyond the regular closing time (Record pp. 13, 14, 16, 19, 27, 31, 197). Nor did the respondents confine their investigations to areas germane to the discovery or production of Krebiozen. The respondents demanded search of premises that do not and never did have any connection with the manufacture of Krebiozen (Record pp. 190, 192, 193, 197).

2. The petitioner does not maintain that individual rights are the only consideration. In making a determination of reasonableness the court must weigh and take into account the conflicting interests, those being the individual's rights to be free from search and the government's right to search in the public interest. The following are examples of the activities engaged in by the agents of the Food and Drug Administration; in none of these examples was there a public benefit commensurate with the great deprivation of personal liberty suffered by the petitioner.

(a) The respondents supplemented their investigations by the taking of a staged photograph which grossly misrepresents the petitioner and has placed him in jeopardy and caused him to suffer great anxiety (Record pp. 12, 13, 17, 19, 20, 23, 28). This photograph creates the erroneous and fraudulent impression that the petitioner was pouring only distilled water into Krebiozen ampules. The respondents have attempted to justify their actions by stating that the photograph was taken to demonstrate the laxity of the petitioner's manufacturing processes. This photograph could not possibly accomplish the stated purpose; it in no way portrays the petitioner's manufacturing process; the demonstration was improvised at the request of the respondents and because this photograph was taken when the laboratory was not open for business, the technician who performs the filling operation was not working. It is not difficult to understand why the respondents have been unable to satisfactorily justify this photograph in terms of a public benefit; the public has and could not benefit from deceitful activities of this nature.

The respondents maintain that the photograph is a reasonable exercise of their authority. The Court in the cases of *Moyer* v. *Brownell,* 137 F. Supp. 594 (1921) and *Gouled* v. *U. S.,* 255 U. S. 298, 41 S. Ct. 261 (1921) did not concur with the respondent's position. It was held therein that any

seizure of papers or other tangible articles of a person by coercion, stealth, or misrepresentation is an unreasonable search and seizure under the Fourth Amendment to the Constitution of the United States.

In support of the decision of the District Court, the court below stated that the petitioner has not shown that the photograph has been published; it further stated that petitioner did not state what use, if any, the Food and Drug Administration intends to make of the photograph in the future. That there was no such showing does not make the taking of the photograph "reasonable," nor does the fact that the FDA may not publish the photograph lessen the petitioner's apprehension of its publication. The court must not adopt a policy whereby individual citizens will have to suffer the apprehension of irreparable injury nor should government agents be permitted to cause individuals to so suffer, with the individual's only hope of redress being subsequent to the occasioning of the injury.

(b) The respondents expanded the scope of their investigation to places which do not and never did have any connection with the manufacture of the drug in question. If the investigators had as their purpose supervision of compliance operations for the enforcement of the Federal Food, Drug, and Cosmetic Act, they could not have accomplished their purpose. Not only is such an inspection not authorized by 21 U. S. C. 374, but such activity could not result in a benefit to the public.

(c) 21 U. S. C. 374 requires "each inspection to be commenced and completed with reasonable promptness." The petitioner has stated that the respondents detained him against his will for more than two hours beyond normal business hours (R. pp. 13, 14). Again the respondents maintain that such a detention was reasonable; they do not, however, enumerate the corresponding benefit that must inure to the public.

(d) In *Davis* v. *U. S.*, the court placed particular emphasis on the time and place of the inspection in a finding that the questioned inspection was reasonable; the court said the fact that the questioned inspection was conducted during business hours and at the place of business all support the conclusion that the inspection was reasonable, 328 U. S. 582, 594, 66 S. Ct. 1256, 90 L. ed 1453, 1460 (1946). The petitioner has stated that the business hours of Promak Laboratories are Monday through Friday, from 9:00 A. M. to 5:00 P. M., and that Saturday is not a working day. The court below has stated that the door of the petitioner's establishment was open; that the petitioner's secretary was working, and that a cash transaction occurred. The District Court and the court below fail to distinguish between leaving a door unlocked and being open for business.

A laboratory is not a commercial establishment similar to a department store or a bank; its operation requires "overtime" work, and its operation, by its nature, prohibits its employees from locking the door and disregarding their responsibilities until the following Monday. It cannot be said that the office of a doctor or an attorney is open if such an individual is working at a time other than the business hours stated on the door. The District Court has adopted a policy which permits inspection of any business establishment at any time and has held that the only criteria of reasonableness is whether the door is unlocked and the premises are occupied. It has not been necessary in this country to lock one's door to prevent unwelcome intruders and an unlocked door is not considered an open invitation to all those desiring admission.

3. The safeguards of the Constitution are meaningless unless there is available a means of enforcing these guarantees. The respondents do not justify their actions in terms of public benefit and they contend justification is unneces-

sary; they maintain that an individual may not enforce his rights under the Constitution for such an action is an unconsented suit against the United States. The District Court and the court below so held.

It is well settled that the United States shall be immune from suit unless it specifically consents thereto. Petitioner does not contest this point, he does however, contest its applicability in the present case.

The respondents in effect wish to avail themselves of this immunity merely because they are agents of the United States government. The claim that any action to enjoin agents of the United States is an action against the sovereign and is thus prohibited. This is not the law. A closer examination will reveal the logical inconsistency of such a proposition. It is elementary that the legislative and executive branches of the government must operate within the confines established by the Constitution. If the former fails to so act the remedy is judicial, through a suit testing the validity of the enactment alleged to be unconstitutional. What then is the individual citizen's remedy against unconstitutional acts by the agents of the executive department? Has he a remedy? The respondents claim the answer to this question is no. They wish to exempt their actions from judicial cognizance by hiding behind a shield of immunity. In other words the defendants ask this court to abandon that system of checks and balances which would have prevented an unconstitutional enactment in the first instance.

The respondents (pp. 25 and 26 Appellees' brief) state:

". . . Although these are nominal defendants, the actual effect of any judgment which could be entered for petitioner would be to restrict the activities of the United States government." The District Court so found stating:

> "This is an unconsented suit against the United States. Though the nominal respondents are employees of the

> United States, the purpose of the action is to enjoin the conduct of an inspection which is specifically authorized by law, 21 U. S. C. 374, and the effect of any judgment which might be entered against the respondents would operate against the United States." (Conclusion of Law No. 1, R. p. 285.)

The doctrine of governmental immunity is not applicable in this case. In determining whether a suit nominally against an officer is against the officer individually or against the sovereign, the crucial question is whether the relief sought is against the sovereign (*Lawson* v. *Domestic & Foreign Corp.*, 337 U. S. 682 (1949)). The petttioner has not asked that the inspections be stopped per se. He has only requested that the court enjoin the respondent from further encroachments on his Constitutional rights (Complaint No. 4 and 5, R. p. 10).

How will this "restrict the activities of the United States Government?" The Fourth Amendment to the Constitution and the Congress, through its enactment of the Federal Food, Drug, and Cosmetic Act, already has spoken in this regard, having established reasonableness as the test of the respondent's authority. Petitioner does not seek relief against the sovereign; he only asks that the Court require the respondents to conform to this standard.

The respondents rely heavily on the case of *Lawson* v. *Domestic & Foreign Corp., id.* The respondents (P. 27, Appellees' brief), state "* * * this suit is *plainly* one against the sovereign within the meaning of the *Lawson* decision." (Emphasis supplied.) Examination of the *Lawson* case shows the contrary is true; this is not a suit against the sovereign.

As is pointed out in the *Lawson* case, it is generally acknowledged that there are only two types of cases in which a restraint may be obtained against the conduct of

governmental officials. They are: (1) when "* * * the statute or order conferring power upon the officer to take action in the sovereign's name is claimed to be unconstitutional." (id. p. 690.) (2) When an officer exceeds his Constitutional authority. The case presently being considered falls within this latter category. The petitioner specifically alleged violation of his Constitutional rights and by implication violation of the Federal Food, Drug, and Cosmetic Act which also requires that the investigations be conducted in a reasonable manner.

The court, in the *Lawson* case, held that "it is a prerequisite to the maintenance of any action for specific relief that the Petitioner claim an invasion of his legal rights—either past or *threatened.*" (Emphasis supplied.) As was pointed out previously, the Petitioner has complied with this requisite. In the *Lawson* case relief was denied because the petitioner did not claim that the administration through its agents acted unconstitutionally or pursuant to an unconstitutional grant.

> "* * * where the officer's powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions. The officer is not doing the business which the sovereign has empowered him to do. He is doing it in a way which the sovereign has forbidden. His actions are *ultravires* his authority and therefore may be the object of specific relief." *Lawson* v. *Domestic & Foreign Corp.*, id. at 689.

4. Summary judgment is aptly described, "as a method of promptly disposing of actions in which there *is no genuine issue as to any material fact* * * *" (54 Am. Jur. § 17); *Reynolds Metals Co.* v. *Metals Disintegrating Co.*, 8 F. R. D. 349, Aff'd. 176 F. 2d 90 (1948); *Rolle Mfg. Co.* v. *Marco Chemicals, Inc.*, 92 F. Supp. 218 (1948); Fed. Rules Civ. Proc., Rule 56 (b, c), 28 U. S. C. A. (emphasis supplied).

A summary judgment may not be granted under federal rule if there be an issue presented as to the existence of *any* material fact, and before such motion shall be granted *all doubts* as to existence of a genuine issue of material fact must be resolved against the party moving for summary judgment, *Sarnoff* v. *Ciagilia,* 165 F. 2d 167 (1948); *Zig Zag Spring Co.* v. *Comfort Spring Corp.,* 89 F. Supp. 410 (1950) (emphasis supplied). Whether the petitioner was subjected to an unreasonable search *is a genuine issue of material fact.* The reasonableness of a search is in the first instance *a substantive determination to be made by the trial court* from the facts of the case, in light of the fundamental criteria laid down by the Fourth Amendment, *Ker* v. *State of California,* 374 U. S. 23, 10 L. Ed. 726, 83 S. Ct. 1623 (1963) (emphasis supplied).

The government has attached to its motion a number of affidavits, including an affidavit by the respondent Robert N. Palmer which is 27 pages long, purporting to detail his investigatory activity, and concluding with 25 specific denials on pp. 24-25 thereof of allegations in the complaint. Thus many questions of fact were presented to the District Court, which it could not be expected to pass upon in "a trial by affidavits."

A summary judgment is proper when the moving party is entitled to judgment as a "matter of law." *Silvary Lighting* v. *Versen,* 10 F. R. D. 507 (1950). In *Guat* v. *Richardson,* 39 N. E. 2d 337, 339, 378 Ill. 626 (1942), the court held that to become a "matter of law" there must be *no* evidence tending to establish petitioner's case (emphasis supplied). In the present case it can not be said that there is *no evidence* supporting the petitioner's contention that his Constitutional rights were unreasonably abridged.

5. The court below stated that "even assuming that the June 1963 inspection was illegal, there was no showing in

the District Court of continued or future inspections of such character or the threat thereof." The petitioner respectfully submits that the court below erred in this regard. The petitioner will be subjected to periodic inspections so long as he engages in manufacturing governed by the Federal, Food, Drug, and Cosmetic Act. Until such a time as petitioner chooses to go out of business he will be subjected to periodic inspections by the agents of the Federal Drug Administration.

6. The District Court in granting the summary judgment stated that the petitioner's affidavits are defective to the extent that the affidavits have been offered by persons having no personal knowledge of some of the matters attested. The petitioner is mystified as to the basis of this conclusion, for upon cursory examination of the record it is seen that the matters attested to in the affidavits were indeed within the personal knowledge of all the persons so making the affidavits. For that matter the petitioner, by his own affidavit has attested to all matters alleged in the complaint. The affidavit of the petitioner in itself is sufficient; injury in the presence of a witness is not a requisite to maintaining an action for the enforcement of an individual's Constitutional rights, and the dissent in the court below states that a trial of the facts should have been held.

CONCLUSION.

For the foregoing reasons this petition for a writ of certioari should be granted.

Respectfully submitted,

JOHN F. SEMBOWER,
Attorney for Petitioner.

APPENDIX A.

UNITED STATES DISTRICT COURT.
(Caption—Civil Action No. 63 C 1133)

FINDINGS OF FACT AND CONCLUSIONS OF LAW.

This cause having come on for hearing on the Defendants' motion to dismiss and for summary judgment of dismissal, and the Defendants having appeared by Frank E. McDonald, United States Attorney for the Northern District of Illinois, and the Plaintiff, Stevan Durovic, having appeared by William & Leonard and Bass & Friend, his attorneys, and the Court having considered the motions, the affidavits submitted in accordance with Rule 56 of the Federal Rules of Civil Procedure and being fully advised in the premises, the Court makes the following:

FINDINGS OF FACT.

1. By letter dated January 14, 1963, the Defendant, Boisfeuillet Jones, Special Assistant (Health and Medical Affairs) to the Secretary, Department of Health, Education, and Welfare, advised the Plaintiff, Stevan Durovic, that an investigation would be initiated under the regulatory laws administered by the Department to determine whether the drug Krebiozen was being manufactured and distributed in accordance with such laws.

2. The investigation began on February 19, 1963, but its first phases were concerned with the collection of medical records in possession of Stevan Durovic at the Krebiozen Research Foundation. These were the medi-

cal records of patients treated with Krebiozen who were claimed by the plaintiff to have been helped by Krebiozen. These phases of the investigation continued until early May. 1963.

3. On April 23, 1963, the inspectors assigned to the investigation advised the Plaintiff that since no more patient records were available, they were ready to begin the inspection into the manufacture and distribution of Krebiozen.

4. Krebiozen is an unapproved new drug which has been distributed since about 1950 for investigational use in the treatment of cancer in man. The inspectors advised the Plaintiff that they were to examine the facts bearing upon when, where, and the circumstances under which Krebiozen was produced and the circumstances attending its interstate distribution.

5. Between May 8 and May 20, 1963, three inspectional visits were made to the premises operated by the Plaintiff under the trade name Promak Laboratories. It is there that Krebiozen is prepared in ampules and shipped interstate.

6. No manufacturing operations were under way during these visits. Ampules labeled as containing the investigational drug were being mailed to interstate consignees. Plaintiff orally advised the inspectors how he carried out his manufacturing practices, and he permitted access for inspection of the manufacturing equipment. Some records of distribution were made available for copying, but this included only parts of the distribution for 1960, 1961, and 1962.

7. Plaintiff represented to the inspectors on May 9, 1963, that the supply of Krebiozen was low—consisting of 356 ampules and 5 to 15 milligrams of Krebiozen powder. The inspectors on May 28, 1963, stated in writing

to the Plaintiff that it appeared that a new production would have to be undertaken if the firm was to continue in business, and advised the Plaintiff of their desire to be present when a new supply was to be produced. The inspectors visited the establishment on June 3 and June 5, 1963 seeking samples of Krebiozen and of the mineral oil used in the ampules. The supply was then 796 ampules which was only enough to fill one day's orders.

8. On June 7, 1963, the Plaintiff, from Washington, D. C., told the inspectors by long-distance telephone that he would not return to Chicago until June 11. He requested that the inspection be delayed until his return. The inspectors stated that they would remain in Chicago available for the inspection should the Plaintiff decide to return earlier to produce a new supply.

9. On June 8, 1963, a Saturday morning, the inspectors visited the address at which the Plaintiff conducts business as Promak Laboratories. Finding the door unlocked, they entered, presented a written notice of inspection to the Plaintiff as required by 21 U. S. C. 374, and proceeded to make an inspection. The Plaintiff protested the inspection on Saturday, but the facts are undisputed that the establishment was open, that ampules of the investigational drug were in preparation for interstate distribution, and that a cash transaction with a customer occurred while the inspectors were present.

10. Plaintiff was in the course of processing approximately 5,000 ampules of the investigational drug. The ampules were held in three metal pails and a plastic pail. Plaintiff identified a metal receptacle which he said contained Krebiozen in mineral oil solution ready for use in filling additional ampules.

11. This solution was transferred by the plaintiff to a glass container which held a small amount of Krebiozen

solution. This container had been used in filling ampules prior to the inspection, and the Plaintiff demonstrated how the ampules were filled from the solution in the glass container. One of the inspectors took a photograph of the glass container, showing that it was labeled as distilled water.

12. This gave rise to a dispute about unfair tactics, and the Plaintiff called three associates to his place of business to hear his protests. The inspectors made a statement to the Plaintiff in the presence of his associates about the photograph and why it was taken.

13. There then ensued a dispute about the inspectors' request for samples of Krebiozen. They requested 100 ampules, from the 5,000 on hand, and 250 milliliters of the solution being used to fill the ampules. The Plaintiff insisted that 3 ampules and 3 milliliters was an adequate sample. After consultation with his attorneys and upon receipt of a written request for the samples, the Plaintiff surrendered the samples over protest and with payment deferred.

14. The inspectors also sought to obtain a sample of the Krebiozen powder being used to produce the ampules. They were advised that the stock of Krebiozen powder was locked in a commercial bank which was closed. Arrangements were made for a return visit early the next week to sample the Krebiozen powder. This visit was deferred several times, at the Plaintiff's request, until a meeting arranged for June 26. When the meeting occurred, the inspectors were served with process in this action which had been initiated that day.

15. Voluminous affidavits have been filed in support of the Defendants' motion for summary judgment. All of these are statements by persons with personal knowledge of facts about which they are competent to testify. The Plaintiff has filed affidavits relevant to the June 8

inspection and in response to the Defendants' assorted need to inspect the records of disposition of a large number of ampules purchased by the Plaintiff in 1950. These affidavits show that there is a large discrepancy between the amount of Krebiozen powder claimed to have been produced by the Plaintiff since 1950 and the amount that would have been needed to dissolve in mineral oil for filling the number of ampules purchased by the Plaintiff since that date. The affidavits show that contradictory statements have been made by the Plaintiff about the supply of Krebiozen powder available for use in preparing ampules. The affidavits further show that examination and analysis of the Krebiozen powder is the most practical way to determine its identity, strength, quality, purity, and safety. The Defendants have filed an affidavit giving the results of the Government's examination of a small sample (2 milligrams) of Krebiozen powder supplied to it by the Plaintiff on July 12, 1963, when he withdrew from interstate commerce, and of a number of ampules produced by the Plaintiff in 1963 and in earlier years. The only controverting affidavit relates to an analysis of material allegedly obtained by extraction from Krebiozen ampules produced in about 1950. This affidavit is unsatisfactory because the affiant had no personal knowledge of the authenticity of the sample and because it gives only a tentative identification. The disputes in the affidavits raise no genuine issue of fact which precludes judgment of dismissal for the Defendants. A thorough and complete investigation is authorized by law, and the Defendants may not be enjoined from making it. There is no dispute of the fact that the Plaintiff has refused inspection of the manufacturing process, of the stock supply of Krebiozen both in ampule and powder form, and of records relating to the interstate distribution of this investigational drug.

CONCLUSIONS OF LAW.

1. This is an unconsented suit against the United States. Though the nominal Defendants are employees of the United States, the purpose of the action is to enjoin the conduct of an inspection which is specifically authorized by law, 21 U.S.C. 374, and the effect of any judgment that might be entered against the Defendants would operate against the United States.

2. The uncontroverted facts show that the inspectors entered the Plaintiff's establishment where prescription drugs for investigational use were being prepared and delivered for introduction into interstate commerce at reasonable times, that they made reasonable requests for inspectional data and samples, and that they conducted themselves with a view to carrying out their statutory duties. The disputed photograph and the dispute about the disposition of ampules purchased in 1950 provide no basis for refusal to permit the inspection of the manufacturing processes, the stock of materials used in production, all finished and unfinished materials, and all distribution records.

3. Nor is there a basis for an injunction which would give the Plaintiff access to the reports made by the inspectors to their superiors, or which would enjoin the Defendants, in their official capacities, from issuing publicity as authorized by law, 21 U. S. C. 375.

4. No claim has been stated in the Complaint upon which relief can be granted.

5. The Defendants have not rested on a motion to dismiss alone, but have filed a properly supported motion for summary judgment of dismissal. Under Rule 56, as amended, when a motion for summary judgment is made and properly supported by affidavits, the Plaintiff may

not rely upon the allegations of his complaint but must file a response by affidavits or otherwise setting forth specific facts to show that there is a genuine issue of fact. Here the response is limited to a very few of the matters asserted in the Plaintiff's affidavits, and it is defective to the extent that affidavits have been offered by persons having no personal knowledge of some of the matters attested. But even aside from this, the record is clear that the inspectors had a right to make the inspection, had reasonable grounds to inquire into the matters covered by the inspection, made reasonable requests for inspection and samples, and that the legally authorized inspections were denied.

6. This case should be dismissed.

Let judgment enter accordingly.

ENTER:

/s/ M. L. IGOE,
Judge.

February 20, 1964

APPENDIX B.

UNITED STATES DISRTICT COURT,
Northern District of Illinois,
Eastern Division.

STEVAN DUROVIC, *Plaintiff*, *vs.* ROBERT N. PALMER, *et al.*, *Defendants.*	Civil Action No. 63 C 1133.

JUDGMENT ORDER.

This cause coming on to be heard on the defendants' motion to dismiss and for summary judgment of dismissal and the court being fully advised in the premises;

And in accordance with its findings of fact and conclusions of law entered herein;

It Is Hereby Ordered, Adjudged And Decreed that the defendants' motion to dismiss and for summary judgment of dismissal is hereby granted.

It Is Further Ordered, Adjudged And Decreed that the complaint be and the same hereby is dismissed.

290 It Is Further Ordered that the plaintiff's motion to expunge certain documents be and the same hereby is denied.

ENTER:

M. L. IGOE,
Judge.

February 20, 1964

APPENDIX C.

IN THE UNITED STATES COURT OF APPEALS,

For the Seventh Circuit.

September Term, 1964—January Session, 1965

No. 14651

STEVAN DUROVIC,
Plaintiff-Appellant,
vs.
ROBERT N. PALMER, R. D. SHERMAN, R. W. CASE, HON. ANTHONY J. CELEBREZZE, BOISFEUILLIET JONES, JOHN H. GUILL, JR.,
Defendants-Appellees.

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.

March 5, 1965

Before CASTLE, *Acting Chief Judge*, DUFFY, SCHNACKENBERG, KNOCH, KILEY and SWYGERT, *Circuit Judges.*

SWYGERT, *Circuit Judge.* This is an appeal from a judgment dismissing an action against the Secretary of Health, Education and Welfare, his Special Assistant, the District Director of the Food and Drug Administration, and three of the latter's agents and inspectors. Plaintiff sought a mandatory injunction requiring defendants to discontinue their inspections and investigation of plaintiff's manufacture and sale of a drug known as

"Krebiozen," a purported treatment for cancer, to surrender a photograph and negatives acquired during an inspection, to produce investigative reports, and to refrain from uttering misleading statements allegedly discrediting plaintiff and his drug.

Upon plaintiff's request for a preliminary injunction, defendants moved for summary judgment and a dismissal of the complaint. The motion for summary judgment was supported by affidavits. Plaintiff filed counteraffidavits. The district court made findings of fact and conclusions of law, then granted the motion for summary judgment and dismissed the action.

Defendants' supporting affidavits showed that the drug Krebiozen had been distributed in interstate commerce by plaintiff. They further showed that although the drug had not been approved under the provisions of section 505 of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. § 355, it had been and was being distributed ostensibly for investigational use under section 505(i) of the act and the regulations issued thereunder.

Plaintiff, as early as 1951, had represented to the Food and Drug Administration that Krebiozen was a white powder soluble both in water and mineral oil and distributed in ampule form. Supposedly all of the Krebiozen powder used between 1949 and 1959 had been brought by plaintiff into the United States from Argentina in the late 1940's. Plaintiff represented that this was enough to manufacture approximately 200,000 ampules. Yet investigation revealed that since 1950 plaintiff had purchased approximately 1,500,000 ampules and enough mineral oil to fill them. This precipitated further investigation by the federal authorities.

According to the affidavits in support of the motion for summary judgment plaintiff claimed to have prepared

Krebiozen powder from horse blood obtained at the Quaker Oats Company's dog food factory at Rockford, Illinois. Investigation showed that in 1959 and 1960 plaintiff had selected and injected approximately 400 horses with a preparation of actinomyces bovis antigen. Three hundred and fifty-eight horses were slaughtered and then bled. The blood was centrifuged to recover the plasma from which the Krebiozen powder was said to have been made.

On February 19, 1963, plaintiff was informed that the Food and Drug Administration would conduct a further investigation to determine whether Krebiozen was being distributed in accordance with federal law and to review the case histories of patients using the drug. Although plaintiff objected to the further investigation, he did submit records of his patients. The additional investigation was conducted at the dog food plant in Rockford and also at the Promak Laboratories in Chicago, owned by plaintiff and used by him for the preparation of his drug. Plaintiff refused a request to furnish records relating to samples of Krebiozen powder. Thereupon, he was notified that the inspectors wanted to observe the preparation of the next mixture of Krebiozen. They visited the Promak Laboratories on June 5, 1963, but plaintiff was out of town. On Saturday, June 8, 1963, the inspectors again visited his establishment. They found him preparing to label ampules freshly filled with mineral oil and Krebiozen powder. The door to the laboratory was open. Plaintiff's secretary was at work, and at least one sale of Krebiozen was made while the inspectors were present. The inspectors saw several containers with filled ampules. Plaintiff told them that these contained Krebiozen and mineral oil. To demonstrate the method of filling the ampules, plaintiff transferred the mineral oil from a drum to a glass container labeled distilled water. The inspec-

tors took a photograph of the bottle. Later and after considerable difficulty, the inspectors obtained as samples for analysis one hundred ampules filled with Krebiozen powder and the mineral oil solution. They also requested a sample of the Krebiozen powder. Plaintiff told them that it was unavailable. Thereafter the inspectors contacted plaintiff several times to obtain a sample of the powder. Plaintiff promised to supply it but failed to keep his promise. Instead, he filed the instant action.

Plaintiff contends that the inspectors exceeded their statutory authority thereby violating his rights under the fourth amendment to the Constitution. He argues that the constitutional prohibition against unreasonable searches and seizures, applicable in determining the legality of inspections under the Federal Food, Drug, and Cosmetic Act, must be rigidly enforced; and further that the question of reasonableness cannot be answered by a fixed formula but must be resolved according to the facts of each case. Plaintiff cites *Davis* v. *United States,* 328 U. S. 582 (1946), for the proposition that the time and place of an inspection are important in determining whether it is reasonable. He then relies on the fact that the inspection here was made on a Saturday at a time when he claims his establishment was not open for business. The facts submitted to the district judge showed, however, that the door to plaintiff's establishment was unlocked, his secretary was at work, the manufacturing process was under way, and a sales transaction took place while the inspectors were present.

Section 704 of the act, 21 U. S. C. § 374, specifically authorizes inspections to be conducted "at reasonable times and within reasonable limits and in a reasonable manner." Under the circumstances here present, we hold that the inspection, although conducted on a Saturday, was a reasonable one and that defendants did not interfere with plain-

tiff's constitutional rights. We think the district judge was justified in concluding that the inspection about which plaintiff complains was conducted at a reasonable time, that reasonable requests were made upon him for data and samples, and that the inspectors "conducted themselves with a view to carrying out their statutory duties."

Plaintiff also contends that the district court erred in granting defendants' motion for summary judgment because there were disputed and genuine issues of material facts. He argues that the affidavits submitted by defendants could not be used to determine the facts in issue since contrary assertions were made in affidavits presented by plaintiff. The district court, however, in granting the summary judgment, noted that plaintiff's affidavits are "defective to the extent that [the] affidavits have been offered by persons having no personal knowledge of some of the matters attested." Fed. R. Civ. P. 56(e) provides that affidavits supporting or opposing a motion for summary judgment "shall be made on personal knowledge." In the absence of such legally sufficient affidavits showing the existence of a genuine issue of fact, summary judgment is authorized. *Engelhard Indus., Inc.* v. *Research Instrumental Corp.*, 324 F. 2d 347 (9th Cir. 1963); *see also G. D. Searle & Co.* v. *Chas. Pfizer & Co., Inc.*, 231 F. 2d 316 (7th Cir. 1956). Accordingly, we hold that the district judge properly invoked the rule permitting summary judgment.

Irrespective of the foregoing determinations, there were additional reasons for the dismissal of the action. It was not shown that the photograph taken by the inspectors had been published, nor was there a showing of what use, if any, the Food and Drug Administration intends to make of the photograph in the future. A similar situation was presented in *American Dietaids Co., Inc.* v. *Cele-*

brezze, et al., 317 F. 2d 658 (2d Cir. 1963). There the question related to the return of tape recordings made during an investigation. We think the observations of the Second Circuit are peculiarly appropriate to the instant situation: "If a civil or criminal action should be brought and if claimed improper use of the tapes is then attempted, motion to discover or suppress the tapes may be appropriate. . . . The courts are reluctant to decide important constitutional questions at a stage of proceedings when the necessity of their resolution has not been established."

With respect to plaintiff's request for an injunction against further investigations and inspections, plaintiff was not entitled to such relief because, even assuming that the June, 1963 inspection was illegal, there was no showing in the district court of continued or future inspections of such character or the threat thereof. Finally, with respect to plaintiff's requests for other injunctive relief which we have heretofore listed, he has not argued these requests on appeal. He therefore must be held to have abandoned them.

The judgment of dismissal is affirmed.

HASTINGS, *Chief Judge*, did not participate in the consideration and disposition of this appeal.

SCHNACKENBERG, *Circuit Judge*, dissenting.

I believe that there should have been a trial rather than disposition by summary judgment.